K063236

XIV. **510(k) Summary** FEB 16 2007

Submitter: Satoshi Noake, International Division, BrainBase Corporation, Tokyo, Japan, Phone: +81-3-3778-0745, Fax: + 81-3-3778-4910.

I. Classification Name and Number: Air Brush (accessory),

II. Product name(s):
II.1. Common or Usual Name: prophy powder, polishing powder
II.2. Proprietary Name: β–Powder

III. Registration No: 3005488486

IV. Compliance with Performance Standards: No performance standards are applicable. However we followed "Class II Special Controls Guidance: Document: Dental Bone Grafting Material Devices", issued April 28, 2005 where applicable because of the materials content.

V. Description of the Device: The β-Powder system is comprised primarily of β-tricalcium phosphate. X-ray diffraction methods were used to identify the crystalline structure. These studies showed that the main constitutent of the device is β-tricalcium phosphate with a small amount of hydroxyapatite, but no other contaminants. Inductively coupled plasma/mass spectroscopy was used for cadmium (Cd) and lead (Pb) analyses, and atomic absorption spectrophotometry was used for mercury (Hg) and arsenic (As). The levels of these harmful elements were below 0.5 ppm

VI. Labels and Labeling: Draft labels of β-powder, instructions for use, warnings and contraindications are provided.

VII. Substantial Equivalence: β - Powder is intended for use as a polishing or prophy powder. This use is the same as that for Clinpro Prophy Powder, cleared in K021450 by 3M Espe Dental Products, and New Prophy Powder, cleared in K014188 by Dentsply, Intl. The materials are the same or similar to those that have been used in commercially marketed products before.

The "510(k) "Substantial Equivalence" Decision-Making Process (Detailed) from ODE Guidance Memorandum #86-3 was followed as described below:

1. These products have the same intended use as predicate devices, for cleaning, polishing, and restoring the natural esthetics of teeth.

2. The technological characteristics for this product are similar to those of the predicate devices and those currently on the market They are fine powders, relatively inert, biocompatible and previously used for periodontal purposes.

3. Descriptive information provided shows that the materials from which this device is made are well-established and well understood in the industry and among professional users.

4. The FDA "Decision-Making Process" chart was used and appears in Appendix V.

(End of Summary)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Satoshi Noake
Brainbase Corporation
Yoneyama 2nd Building 6F,
22-13, Oi 1-chome
Shinagawa-ku, Tokyo Japan 140-0014

FEB 16 2007

Re: K063236
Trade/Device Name: β-Powder
Regulation Number: 872.6080
Regulation Name: Airbrush
Regulatory Class: II
Product Code: KOJ
Dated: February 5, 2007
Received: February 9, 2007

Dear Mr. Noake:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

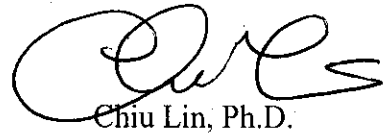
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

XII. Indications for Use

510(k) Number: (not assigned)

Device Name: β - Powder

Indications for Use:

Cleaning, polishing and restoring natural esthetics of tooth enamel.

Prescription Use ✓ or Over-The-Counter Use _____
(Per 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number K062236